



## UNITED STATES AIR FORCE RESEARCH LABORATORY

---

### TESTING AND EVALUATION OF THE VITAL SIGNS, INC., MODELS: VITAL BLUE (ADULT) & CODE BLUE (ADULT), PEDI BLUE (CHILD), AND BABY BLUE (INFANT) MANUAL RESUSCITATORS

MSgt Butch O. Blake

AIR FORCE RESEARCH LABORATORY  
HUMAN EFFECTIVENESS DIRECTORATE  
BIODYNAMICS & PROTECTION DIVISION  
SYSTEMS RESEARCH BRANCH  
2504 Gillingham Dr. , STE 25  
Brooks AFB, Texas 78235-5104

February 2000

Approved for public release; distribution unlimited.

DTIC QUALITY INSPECTED 3

20000517 066

## NOTICES

This final technical report was submitted by personnel of the Protection Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency, contractor, or subcontractor thereof. The views and opinions of the authors expressed herein do not necessarily state or reflect those of the United States Government or any agency, contractor, or subcontractor thereof.

When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use or sell any patented invention that may in any way be related thereto.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

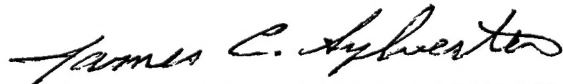
This report has been reviewed and is approved for publication.

Government agencies and their contractors registered with Defense Technical Information Center (DTIC) should direct requests for copies to: Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Ft. Belvoir, VA 22060-6218.

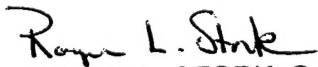
Non-Government agencies may purchase copies of this report from, National Technical Information Services (NTIS), 5285 Port Royal Road, Springfield, VA, 22161-2103.



BLAKE, BUTCH O., MSgt, USAF  
NCIOC, Air Force Medical Equipment  
Development Laboratory



JAMES C. SYLVESTER, Major, USAF, NC  
Chief, Air Force Medical Equipment  
Development Laboratory



ROGER L. STORK, Colonel, USAF, BSC  
Chief, Biodynamics Protection Division

# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE February 2000	3. REPORT TYPE AND DATES COVERED Final, March 1999
4. TITLE AND SUBTITLE  Testing and Evaluation of the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators.			5. FUNDING NUMBERS  PE: 62202F PR: 7184 TA: 56 WU: 01
6. AUTHOR(S)  Butch O. Blake, MSgt			8. PERFORMING ORGANIZATION REPORT NUMBER  AFRL-HE-BR-TR-2000-0030
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Air Force Research Laboratory Human Effectiveness Directorate Biodynamics Protection Division 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104			
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)			10. SPONSORING/MONITORING AGENCY REPORT NUMBER
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION/AVAILABILITY STATEMENT  Approved for public release; distribution unlimited.			12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 words)  The Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators are hand held lightweight, manual resuscitators. The units provide clinicians a way to maintain ventilatory support for patients with life-threatening airway disorders. The units operate by manually squeezing the plastic reservoir bag to create a positive airflow to expand the patient's lungs.			
14. SUBJECT TERMS Vital Signs      manual      resuscitator Ambu      aeromedical Airworthy      aircraft			15. NUMBER OF PAGES  12
			16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT  Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE  Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT  Unclassified	20. LIMITATION OF ABSTRACT  UL

## TABLE OF CONTENTS

BACKGROUND .....	1
DESCRIPTION.....	1
PROCEDURES .....	2
INITIAL INSPECTION AND TEST PREPARATION .....	2
TEST SETUP.....	3
PERFORMANCE CHECK .....	3
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS .....	4
HYPOBARIC CONDITIONS .....	4
AIRBORNE PERFORMANCE.....	5
EVALUATION RESULTS .....	5
INITIAL INSPECTION .....	5
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS .....	5
HYPOBARIC CONDITIONS .....	6
AIRBORNE PERFORMANCE.....	6
SUMMARY .....	6
REFERENCES .....	7
APPENDIX.....	8

## LIST OF FIGURES

Figure 1. Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators .....	1
Figure 2. Test Setup .....	3

# **TESTING AND EVALUATION OF THE VITAL SIGNS, INC., MODELS VITAL BLUE (ADULT) & CODE BLUE (ADULT), PEDI BLUE (CHILD), AND BABY BLUE (INFANT) MANUAL RESUSCITATORS**

## **BACKGROUND**

Headquarters Air Mobility Command (AMC) requested the Air Force Medical Equipment Development Laboratory's (AFMEDL) participation in evaluating and approving the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators for use on board USAF aeromedical evacuation aircraft. Specific components of the manual resuscitators that underwent the evaluation process included the oxygen tubing, reservoir tubing, bag, pressure relief cap, pressure relief valve, valve assembly, swivel flange/ elbow, duck bill valve, sensing pressure port and cap, deflector cap or expiratory port option-peep valve and mask (optional). Throughout this report, the term Equipment Under Test (EUT's) refers to all models of manual resuscitators.

## **DESCRIPTION**

The EUT's are hand held lightweight, manual resuscitators. The EUT's provide clinicians a way to maintain ventilatory support for patients with life-threatening airway disorders. The EUT's operate by manually squeezing the plastic reservoir bag to create a positive airflow to expand the patient's lungs (Figure 1).

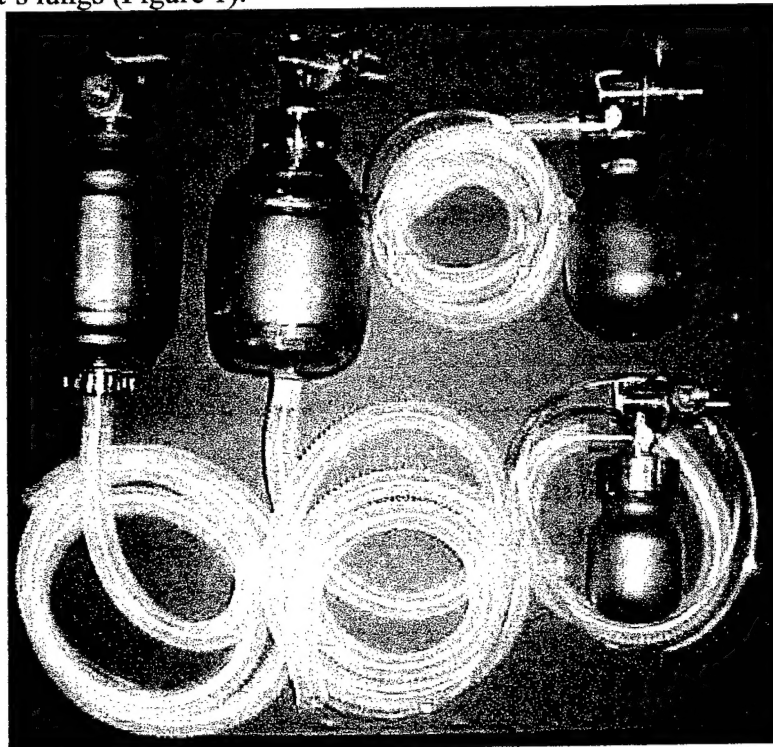


Figure 1. Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators

## **PROCEDURES**

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-5), and manufacturer's literature (6). The AFMEDL Flight Performance Evaluation Procedure Guide and Testing Standards describes additional safety and human interface issues to be considered during equipment testing (7). A test setup and performance check were developed specific to these EUT's to verify their proper functioning under various test conditions. All tests were conducted by AFMEDL personnel assigned to the Protective Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted.

The EUT's were subjected to various laboratory and in-flight tests to observe and evaluate their performance under anticipated operational conditions.

1. Initial Inspection
2. Thermal/ Humidity Environmental Conditions, encompassing:
  - a. Hot Operation
  - b. Cold Operation
  - c. Humidity Operation
  - d. Hot Temperature Storage
  - e. Cold Temperature Storage
3. Hypobaric Conditions
  - a. Cabin Pressure/Altitude
  - b. Rapid Decompression to simulated flight level
4. Airborne Performance

## **INITIAL INSPECTION AND TEST PREPARATION**

- a. The EUT's were inspected for quality of workmanship, production techniques and pre-existing damage.
- b. The EUT's were checked to ensure they met safety requirements and operating Characteristics established in National Fire Protection Agency (NFPA) 99 (1), and AFI 41-201,

## Equipment Management in Hospitals (3).

c. The EUT's were examined to ensure they met basic requirements for human factor design as outlined in MIL-STD 1472E (4).

d. The test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various test conditions.

## TEST SETUP

The EUT's were prepared for tests as follows:

1. Connect EUT's output to Michigan Instruments lung simulator's input port
2. Connect EUT's oxygen tubing to 100% oxygen
3. Squeeze adult manual resuscitators at a rate of 5:1 (one breath every 5 seconds)
4. Squeeze child and infant manual resuscitators at a rate of 3:1 (one breath every 3 seconds)

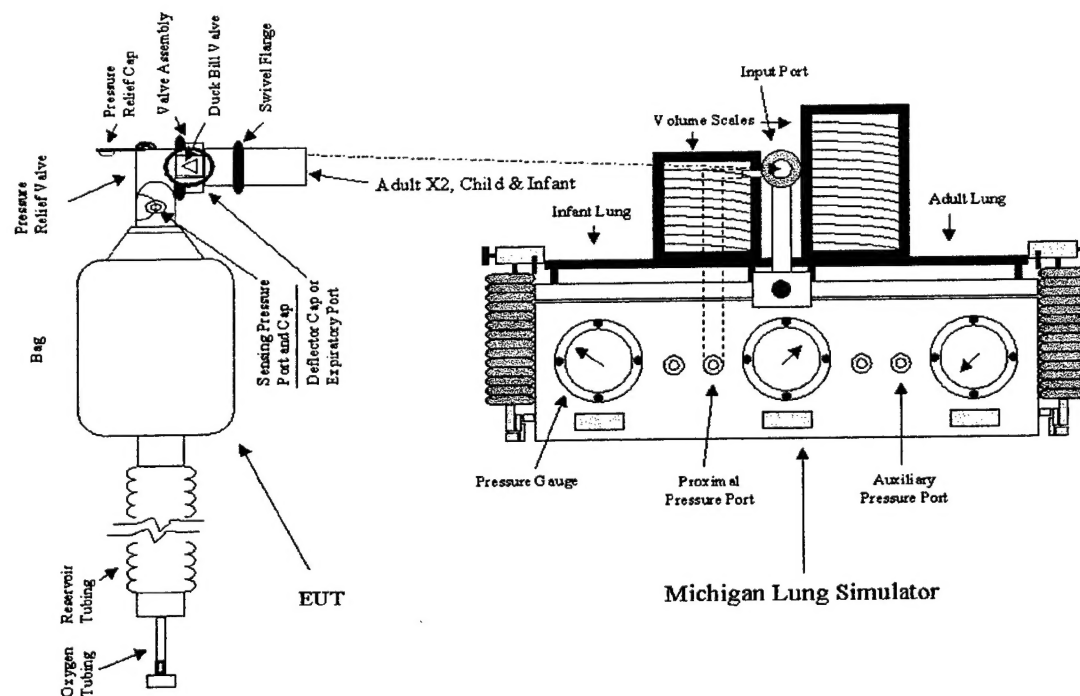


Figure 2. Test Setup

## PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT's during each of the test conditions: The EUT's were prepared for test described. After one full minute



data was taken in several modes. Resistance factors were determined by use of appropriate sized Michigan Instruments Pneu-Flow resistors. For the adult resuscitators, O<sub>2</sub> percentage was taken with a compliance of 0.02 l/cmH<sub>2</sub>O and 0.05 l/cmH<sub>2</sub>O and resistance factors of 20 and 5. For the child resuscitator a compliance of 0.01 l/cmH<sub>2</sub>O and a resistance factor of 50, and for the infant resuscitator a compliance of 0.001 and a resistance factor of 200 were used.

### **THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS**

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (5). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, mechanical failures due to rapid water, or frost formation.

Testing was conducted in a calibrated Thermotron Industries, model SM-32 environmental chamber. The EUT's were placed in the center of the environmental chamber. The other components of the test setup remained outside the chamber. For operational tests, the EUT's were monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT's were placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity:  $94 \pm 4\%$  RH,  $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$  ( $29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ) for 4 hr
- b. Hot Temp Operation:  $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$  ( $49^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ) for 2 hr
- c. Cold Temp Operation:  $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$  ( $0^{\circ}\text{C} \pm 4^{\circ}\text{C}$ ) for 2 hr
- d. Hot Temp Storage:  $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$  ( $60^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ) for 6 hr
- e. Cold Temp Storage:  $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$  ( $-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ) for 6 hr

### **HYPOBARIC CONDITIONS**

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. The majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation pressurize their cabins to barometric pressures equivalent to 8,000 - 15,000 ft above sea level. The differences in pressure affect the operation of some medical equipment. Altitude testing consisted of operating the EUT's while ascending from ground level to 15,000 ft. Ascent was stopped at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is



important to assess medical equipment performance during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT's were placed inside the rapid decompression test chamber and the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more with a 7-second RD and a 1-second RD. The EUT's were monitored throughout the series of decompressions. Performance checks were assessed each time the EUT's returned to ground level and components examined for damage.

## **AIRBORNE PERFORMANCE**

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on a C-9 aeromedical evacuation mission conducted this phase of testing. The EUT's were taken out of their protective plastic bag and used in various areas of the aircraft. Then human factor characteristics were evaluated, e.g., (securing methods, setup/tear down times and securing locations evaluated.) Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT's human factor considerations.

## **EVALUATION RESULTS**

### **INITIAL INSPECTION**

Initial inspection revealed no manufacturing defects. The units performed to the manufacturer's specification.

### **THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS**

The EUT's were evaluated IAW manufacturer's guidelines regarding hot operation, cold operation, and humidity. The EUT's operated according to AFMEDL and manufacturer's guidelines during hot and cold operation, hot and cold storage, and humidity testing.

## **HYPOBARIC CONDITIONS**

1. Cabin Pressure/Altitude: The EUT's performed in accordance with manufacturer's specifications throughout testing. The EUT's were able to deliver O<sub>2</sub> percentages above 95% when supplied with 100% oxygen at 10 lpm.
2. Rapid Decompression: The EUT's operated satisfactorily following each decompression event.

## **AIRBORNE PERFORMANCE**

The in-flight evaluation of the EUT's was performed on a C-9 aeromedical evacuation mission. It was determined that the EUT's were simple to use and store on the aircraft.

## **SUMMARY**

AFMEDL found the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft. Its operation was within expected parameters under environmental extremes and simulated cabin altitudes. It did not produce a hazard to patient or crew during rapid decompression.

Any public announcement of this final report shall be coordinated between Vital Signs, Inc., AFRL, AFMEDL and the Brooks AFB Public Affairs Office. Vital Signs, Inc. shall not use the name of the Air Force Activity or the Government on any product or service, which is directly or indirectly related to this final report. This laboratory or the Government does not directly or indirectly endorse any product or service provided, or to be provided, by Vital Signs, Inc. its successors, assignees, or licensees. Vital Signs, Inc. shall not in any way imply that this technical report is an endorsement of any such product or service.

## REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-201, Equipment Management in Hospitals
4. MIL-STD 1472E, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
6. Vital Signs, Inc., Models Vital Blue & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators, Operation Instructions.
7. AFMEDL Flight Performance Procedures Guide and Testing Standards, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.